JUL 2 9 2003

K031647

510(K) SUMMARY

Prepared on May 2, 2003

Submitter: Getinge USA, Inc.
1777 East Henrietta Road
Rochester, NY 14623

Contact Person: Karla Byrne, Operations Director Consumable Products Division
Telephone: (585) 272-5007 Fax: (585) 272-5271

Common Name: Biological Sterilization Test Pack
Propietary Name: Biosign SSI Test Pack with Instant Readout Integrator

Classification: Indicator, Biological Sterilization Process – Class II, 80 FRC

Predicate Device: Castle Biosign EZ-VU Biological Test Pack (K922212)
SteriTec Biological Test Pack with Instant Readout Integrator (K001444)

Device Description:
The Getinge Biosign SSI Test Pack with Instant Readout Integrator is a test pack designed specifically for biological testing of steam 132°C pre-vacuum sterilization cycles. When used to monitor steam 132°C pre-vacuum cycles, the product is intended to give the user an instant reassurance based on a result from a steam integrator card, and after biological indicator incubation, even greater assurance that the sterilizer operated at proper sterilization parameters.
The Biosign SSI Test Pack with Instant Readout Integrator is constructed using a self-contained Geobacillus stearothermophilus biological indicator (10^4spores/strip), placed inside a small package of porous and nonporous materials, and includes a steam integrator card. The package simulates the biological indicator 16-towel test pack as defined by ANSI/AAMI ST46-1993. The instant readout integrator card provides immediate verification that the test pack was exposed to sterilization parameters, when the word "PASS" imprinted with a purple indicator ink, changes to green. The biological indicator gives an even greater assurance that sterilization occurred, when the incubated spores display no growth, as indicated by no color change (red) in the growth media.

The shelflife of the new Biosign SSI Test Pack with Instant Readout Integrator is the same as the predicate Biosign EZ-VU Test pack (18 months). The biological indicator is the generally limiting factor and the shelflife of the product can never go beyond the shelflife of the biological indicator, or the shelflife of the integrator card, whichever is shortest.

The Getinge Biosign SSI Test Pack with Instant Readout Integrator is the same size as, utilizes the same materials and is constructed the same as the Biosign EZ-VU Test pack, only with the addition of the instant readout indicator card printed with the integrator ink utilized in the SteriTec Biological Test Pack with Instant Readout Integrator. Since the integrator card was designed to function inside a test pack, its placement in the biological test pack offers no difference in functional environment. The same Biosign biological indicator with Geobacillus stearothermophilus is utilized in the Biosign SSI Test Pack with Instant Readout Integrator, as is used in the Biosign EZ-VU Test pack.

Intended Use:

The Getinge Biosign SSI Test Pack with Instant Readout Integrator is a steam sterilization monitor designed specifically for biological testing of pre-vacuum steam sterilizers operating at 132°C. The instant readout integrator card gives the operator a prediction of the biological test outcome.

Comparison to Predicate Device:

The Getinge Biosign SSI Test Pack with Instant Readout Integrator's functional parameters, manufacturing materials, and storage conditions are the same as the Getinge Biosign EZ-VU Test Pack with the addition of the Instant Readout Indicator card. The Instant Readout Integrator Card's functional parameters and manufacturing materials are the same as the Instant Readout Integrator Card in the SteriTec Biological Test Pack with Instant Readout Integrator.

Description of Testing:

Samples from 3 different lots of Biosign SSI Test Pack with Instant Readout Integrator were run at steam 132° pre-vacuum for various exposure times. For comparison, different lots of Biosign EZ-VU Test Pack and SteriTec Biological Test Pack with Instant Readout Integrator were also run at steam 132°C pre-vacuum. Testing was conducted in a validated BIER unit and in a Getinge straightline sterilizer.

Conclusion:

The Getinge Biosign SSI Test Pack with Instant Readout Integrator is substantially equivalent to the Castle Biosign EZ-VU Biological Test Pack and the SteriTec Biological Test Pack with Instant Readout Integrator for monitoring pre-vacuum steam sterilizers operating at 132°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2003

Ms. Karla Byrne
Consunabie Products Operations Director
Getinge USE, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K031647
Trade/Device Name: Biosign SSI Biological Test Pack with Instant Readout Integrator
Regulation Number: 880. 2800
Regulation Name: Sterilzation Process indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 13, 2003
Received: May 28, 2003

Dear Ms. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

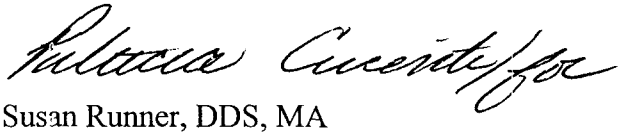
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K031647

Device Name: Biological Test Pack with Instant Readout Integrator

Indications For Use:
The Getinge Biosign SSI Test Pack with Instant Readout Integrator is a steam sterilization monitor designed specifically for biological testing of pre-vacuum steam sterilizers operating at 132°C. The instant readout integrator card gives the operator a prediction of the biological test outcome. When the chemical integrator "PASS" changes from purple to green, it indicates correct exposure conditions of temperature, time and steam.

SRB for Chiu Lin
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031647

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)